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REMARKS

I. Examiner Interview

The undersigned attorney and Applicants wish to thank the Examiner for the courtesy of the telephonic interview which occurred 3 February 2005. The following remarks correspond to Applicants' arguments which were presented to the Examiner during the interview.

II. Claim Rejection – Double Patenting

Obviousness-type double patenting is the only rejection set forth in the outstanding final Office Action. All pending claims are rejected for obviousness-type double patenting in view of a combination of two or more patents. Each double patenting rejection is at least based on the commonly owned US 6,633,792 (the "792 patent"), issued October 14, 2003, to Folestad et al. ("Folestad") in combination with US 5,750,996 to Drennen, III et al. ("Drennen"). With respect to certain claims, Folestad and Drennen are combined with yet a third and fourth reference to support the rejection. The double patent rejections are summarized in the following table:

CLAIMS	CITED PATENTS	
1, 2, 7-9, 13-18, 20, 22-25, 27, 31, 32, 37-39, 41, 47, 48 and 53	Folestad + Drennen	
4-6, 28-30, 35 and 36	Folestad + Drennen	US 4,125,391 to Van Laethem ("Van Laethem")
10, 33, 42-44 and 50	Folestad + Drennen	US 4,993,264 to Cody et al. ("Cody")
11 and 45	Folestad + Drennen	US 6,038,525 to Maguire et al.
12, 34, 46 and 52	Folestad + Drennen	Van Laethem + US 6,248,363 to Patel et al.
19 and 40	Folestad + Drennen	US 5,420,681 to Woodruff
49 and 51	Folestad + Drennen	Van Laethem + Cody

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III. The Claimed Invention

The claimed invention is characterized by the concurrent performance of three process steps:

- (a) a particle levitates or floats at a given location;
- (b) the same particle is coated while it levitates or floats at the given location; and
- (c) a spectroscopic measurement is performed on the coating while the same particle levitates or floats at the given location.

IV. Folestad

The Examiner alleges that the primary reference to Folestad teaches the spectrometric measurement of a coating on a pharmaceutical product during the actual process of coating the product. The Examiner relies on claim 10.

Applicants submit that claim 10 can only be properly construed when considered together with claims 9 and 11 in light of the corresponding disclosure at column 3, lines 38-47. For the Examiner's convenience, claims 9-11 are reproduced below:

- 9. The method according to claim 1, wherein the step of performing a measurement on said coating is carried out on a sample at any stage of the coating process.
- 10. The method according to claim 1, wherein the step of performing a measurement on said coating is carried out on a sample within a coating vessel during the actual coating process.
- 11. The method according to claim 1, wherein the step of performing a measurement on the coating is carried out on a final product in order to determine the quality of the coating.

A. Claims 9 -11 of Folestad provide a time frame for performing a spectrometric measurement.

Claim 9 of Folestad broadly defines the period of time for taking a spectrometric measurement. Specifically, claim 9 states that the measurement is taken "at any stage of the

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coating process". The term "stages", as used in claim 9, is defined by The American Heritage Dictionary (2nd College Edition) to mean "a period of time in the course of a process".

Therefore, a spectrometric measurement according to Folestad can be taken during or after the coating process, i.e., claims 10 and 11, respectively.

Therefore, claims 9-11 provide a time frame for performing the spectrometric measurement of claim 1, step (a). Although claims 9-11 specify when the spectrometric measurement is performed, Applicants respectfully submit that claims 9-11 do not disclose or suggest that the spectrometric measurement is performed on a sample while the same sample is being coated. This interpretation is fully supported by the corresponding disclosure appearing at column 3, lines 41-44 of the specification:

The measurements can be performed during the actual coating process, e.g. within a coating vessel or by taking out a sample from the coating vessel without interrupting or interfering with the coating process.

The disclosure that the spectrometric measurement can be performed by removing a sample from the coating vessel during the actual coating process is convincing proof that the expression "actual coating process", as used in claim 10, is applicable in a general sense to the manufacturing process itself and not to the coating of a specific particle. In other words, it is possible in accordance with Folestad to take an off-line spectrometric measurement of a coating while the actual coating process continues in the coating vessel. The disclosure of an off-line measurement while the actual coating process remains in progress is strong evidence that Folestad is not concerned with the performance of a spectrometric measurement on a sample while the same sample is being coated.

Therefore, claim 10 must be construed to mean that a spectrometric measurement is performed while the actual coating process is, generally speaking, in progress. This is true whether the measurement takes places within or outside of the coating vessel. However, claim 10 does not disclose or suggest that the spectrometric measurement is performed on a sample while the same sample is being coated.

B. The spectrometric measurement of claims 9 and 10 of Folestad is performed on a sample.

As discussed in the previous section, claim 9 of Folestad provides that the spectrometric measurement of claim 1 is carried out at any stage of the coating process, i.e., during the actual coating process (claim 10) and after the coating process (claim 11). Claim 9 further provides that the measurement is carried out on a sample at any stage of the coating process. Claim 10 is specifically directed to the embodiment wherein the measurement is performed on a sample within the coating vessel during the actual coating process, whereas claim 11 is directed to the embodiment wherein the measurement is performed on a final product after the coating process.

Applicants submit that the term sample, as used in claims 9 and 10, is entitled to its ordinary meaning. There is nothing in the specification to suggest otherwise. Therefore, as defined by Merriam-Webster OnLine, a sample is understood to mean:

a representative part or single item from a larger whole or group especially when presented for inspection or shown as evidence of quality. (www.m-w.com)

Similarly, the McGraw-Hill Dictionary of Scientific and Technical Terms (2nd Edition) defines sample to mean:

a selection of a certain collection from a larger collection.

Thus, the ordinary meaning of the term sample implies the act of selecting a fraction from a population and presenting the selected fraction, as representative of the population, for inspection.

The ordinary dictionary meaning of sample comports with the technical literature. For example, the following disclosure appears in Leon Lachman et al., "The Theory and Practice of Industrial Pharmacy", 3rd Edition (1986):

SAMPLING AND SAMPLING PLANS

Sampling may be defined as *the process of removing an appropriate number of items from a population in order to make inferences to the entire population*. The object of sampling and subsequent testing, in the present context, is to provide an effective check on the quality of the product or substances being processed. Representative of materials to be sampled are drug substances, raw materials, intermediate products, and final products before, during, and after manufacturing and packaging operations. The quality control inspector must be empowered to sample at any point or stage of manufacturing and packaging operations. Proper methods of sampling and adequate number and size of samples are needed for an effective quality assurance program, since the judgment "accept" or "reject" is made on the basis of the sample, irrespective of the conditions in the remainder of the batch. (Italics original; bold added)

Therefore, based on the ordinary meaning given to the term "sample", claim 9 is interpreted to mean that a representative sample of coated particles is selected from the population of coated particles and presented for spectrometric measurement at any stage of the coating process. With specific regard to claim 10, the spectrometric measurement takes place on the selected sample in the coating vessel while the actual coating process remains in progress with respect to the remaining population. Therefore, Folestad does not disclose or suggest the performance of a spectrometric measurement on a sample while the same sample is being coated. There is nothing in the specification to suggest otherwise. Applicants' interpretation comports with the express purpose and advantage of the invention of Folestad as stated at column 3, lines

41-44: "The measurements can be performed during the actual coating process...without interrupting or interfering with the coating process."

V. Drennen

In accordance with Drennen, coating and measurement are separate events occurring at different times in different locations in the coating chamber. Specifically, as shown in Figures 1 and 2, particles 49 are coated in inner chamber 10 of coating chamber 2. The coated particles exit inner chamber 10 and travel downwardly through annular passage 14. Probe 20 has an upwardly open recess 24 which itself has an enlarged portion 26 to facilitate entry of a coated particle during its descent in annual passage 14. Upon entry in open recess 24, the coated particle is trapped and then measured.

Therefore, Drennen does not disclose or suggest coating a particle and measuring the coating on the same particle at the same time and at the same spatial location.

VI. There Is No Double Patenting

For all of the forgoing reasons, the claimed invention is not an obvious variant of Folestad in light of Drennen. Neither Folestad nor Drennen, whether taken alone or in combination, discloses or suggests the performance of a spectrometric measurement on a sample while the same sample is being coated. None of the other cited patents, i.e., Van Lathem, Cody, Maguire, Patel and Woodruff, overcomes this deficiency.

For all of the foregoing reasons, Applicants submit that there is no double patenting. Withdrawal of the obviousness-type double patenting rejection is requested.

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CONCLUSION

Applicants submit that pending claims 1, 2, 4-20, 22-25 and 27-53 are in condition for allowance, which action is earnestly solicited. The Commissioner is hereby authorized to charge Deposit Account No. 23-1703 in the event that any fee is required in connection with this communication.

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Respectfully submitted,



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